510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
KO41439

B. Purpose for Submission:
New device clearance

C. Analyte:
Influenza Type B nucleoprotein antigens

D. Type of Test:
Lateral flow immunochromatographic assay

E. Applicant:
SA Scientific, Inc.

F. Proprietary and Established Names:
SAS Influenza B Test, SAS FluB Test

G. Regulatory Information:

1. Regulation section:
   21 CFR Part 866.3330
2. Classification:
   Antigens, CF (including CF Control), Influenza virus A, B, C
3. Product Code:
   GNX
4. Panel:
   83 Microbiology

H. Intended Use:

1. Intended use(s):

SAS™ Influenza B Test is a visual and rapid assay for the presumptive qualitative detection of Influenza Type B antigens from nasal washes and aspirates. Negative results should be confirmed via cell culture. This test is not intended for the detection of Influenza Type A or C viral antigen. This test is for professional use only.

2. Indication(s) for use:

NA

3. Special condition for use statement(s):

The device is for prescription use only

4. Special instrument Requirements:

NA

I. Device Description:

The SAS™ Influenza B test utilizes monoclonal antibodies against Influenza Type B viral nucleoproteins. The test begins with an extraction of Type B nucleoproteins. Extracted specimens are then added to the test device. If type B nucleoproteins are present they bind to the antibody- gold conjugate in the test membrane and form a complex. This complex migrates across the membrane and is captured by Type B antibody in the membrane. Thus, in the presence of Influenza Type B nucleoproteins, a "whole sandwich" immuno-complex is formed and a visible, pink colored line develops in the specimen zone of the test device. In the absence of an Influenza Type B antigen, a "sandwich" immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink colored control line should appear in the control zone regardless of the presence or absence of Influenza Type B nucleoproteins.

The device is provided in kit form, the contents are as follows.

Test Devices.
Extraction buffer.
Disposable extraction tubes and filter tips.
Package insert.

J. Substantial Equivalence Information:

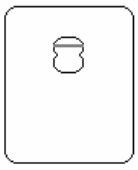
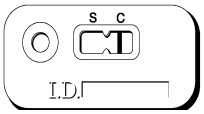
1. Predicate device name(s):

Binax™ NOW® Flu B Test (K021649) manufactured by Binax™ Inc., Portland, Maine.

2. Predicate K number(s):

K021469

3. Comparison with predicate:

	Viral Culture	Binax™ NOW® Flu B	SAS™ Influenza B Test
Format	Viral Culture	Lateral Flow	Lateral Flow
Cassette	N/A		
Antibodies	Monoclonal antibody	Antibodies to nucleoprotein	Monoclonal antibodies to nucleoprotein
Sample Type	Nasopharyngeal Specimens	Nasopharyngeal Specimens	Nasopharyngeal Specimens
Sample Size	200 µl	100 µl	150 µl
Method of Detection	CPE Immunofluorescen	Latex	Colloidal Gold

	ce		
Assay Time	24-48 hours	15 minutes	15 Minutes

K. Standard/Guidance Document Referenced (if applicable):
NA

L. Test Principle:
The test begins with an extraction of Type B nucleoproteins. Extracted specimens are then added to the test device. If type B nucleoproteins are present they bind to the antibody- gold conjugate in the test membrane and form a complex. This complex migrates across the membrane and is captured by Type B antibody in the membrane. Thus, in the presence of Influenza Type B nucleoproteins, a "whole sandwich" immuno-complex is formed and a visible, pink colored line develops in the specimen zone of the test device. In the absence of an Influenza Type B antigen, a "sandwich" immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink colored control line should appear in the control zone regardless of the presence or absence of Influenza Type B nucleoproteins.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. ***Precision/Reproducibility:***

The reproducibility of the SAS™ Influenza B Test was evaluated in three clinical laboratories. The SAS™ Influenza B Test was tested against a panel of five (5) specimens of which included two (2) levels of positives and three (3) negatives over three days by three (3) laboratory personnel. The low and medium positive were from the Influenza B H1N1 strain. Negatives were comprised of sample extraction buffer, *Streptococcus Group B* and Influenza A Aichi strain. The overall reproducibility for the SAS™ Influenza B Test was 100%.

b. Linearity/assay reportable range:
NA

c. Traceability, Stability, Expected values (controls, calibrators, or method):
NA

d. Detection limit:

The limit of detection (LOD) or the SAS™ Influenza B Test was determined for five (5) Influenza B Viral Strains.

Influenza B Viral Strain	**ATCC**	**Concentration $TCID_{50}$/0.2 ml**
B/Lee/40	VR101	1.2×10^5
B/Allen/45	VR102	5.6×10^2
B/Mass/3/66	VR523	3.2×10^3
B/Taiwan/2/62	VR295	7.9×10^3
B/Maryland/1/59	VR296	4.5×10^5

e. Analytical specificity:

To confirm the analytical specificity of the SAS™ Influenza B Test, fifteen (15) bacterial and twenty-one (21) viral strains likely to be found in the respiratory

tract were tested. Bacterial cultures were tested at 1 x 10^8 cfu/ml and the viral cultures at 5.6 x 10^3 to 5.6 x 10^6 $TCID_{50}$/0.2 ml. All yielded negative results.

f. Assay cut-off:

NA

2. Comparison studies:

a. Method comparison with predicate device:

Multiple clinical sites tested two hundred fifty-five (255) clinical specimens blindly and prospectively using the SAS™ Influenza B Test and Cell Culture or DFA. The SAS™ Influenza B tests and Cell Culture had an overall agreement of 99%.

		Cell Culture/DFA		
		+	-	
SAS Influenza B	+	19	0	19
Test	-	2	234	236
		21	234	255

Sensitivity (19/21) x 100 = 90.5% (95% CI, 71.1% to 97.4%)
Specificity (234/234) x 100 = 100% (95% CI, 98.4% to 100%)
Agreement (253/255) x 100 = 99.2% (95%CI, 97.2% to 99.8%)

b. Matrix comparison:

NA

3. Clinical studies:

a. Clinical sensitivity:

Multiple clinical sites tested two hundred fifty-five (255) clinical specimens blindly and prospectively using the SAS™ Influenza B Test and Cell Culture or DFA. The SAS™ Influenza B tests and Cell Culture had an overall agreement of 99%.

		Cell Culture/DFA		
		+	-	
SAS Influenza B	+	19	0	19
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		21	234	255

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Agreement (253/255) x 100 = 99.2% (95%CI, 97.2% to 99.8%)

b. Clinical specificity:

See above

c. Other clinical supportive data (when a and b are not applicable):

NA

4. Clinical cut-off:

NA

5. Expected values/Reference rang

The number of influenza virus infections varies from year to year, and they primarily occur during the fall and winter months. Many factors contribute to the rate of positivity, which include test method, geography, disease prevalence in the community and sampling method. Influenza B infections occur less than that of Influenza A. The multiple center clinical trial conducted over 2003 and 2004 Influenza Season had a prevalence of 8% when compared to cell culture/DFA and 7% when compared to SAS™ Influenza B Test results.

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.